REMARKS

Reconsideration of this application is requested. Claims 37-145, 148, 150-156, 158-162, 164-167, 169, 171, 173-179, 181-184,186 and 191-197 are in the case.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "**Version With Markings To Show Changes Made**."

I. THE INTERVIEW

At the outset, the undersigned wishes to thank the Examiner (Mr. Choi) and his supervisor (Mr. Pak) for kindly agreeing to conducting a personal interview on this application. The interview was held on April 9, 2002. The courtesies extended by the Examiner and his supervisor were most appreciated. The substance of the interview will be clear from the comments presented below.

II. INFORMATION DISCLOSURE STATEMENT

The comments appearing in the first paragraph on page 2 of the action have been noted. Attached is a completed PTO-1449 together with copies of the listed references and the IDS fee. The Examiner is requested to initial the

attached PTO-1449 and return a copy of the initialed document to the undersigned with the next paper to issue in this application.

III. ELECTION/RESTRICTION

Claims 187-190 have been indicated as withdrawn from consideration. In response, and without conceding to the merit of this rejection, Claims 187-190 have been canceled without prejudice.

IV. CLAIM OBJECTIONS

Claim 37 has been objected to for the reasons stated on page 3 of the action. In response, Claim 37 has been amended so as to begin with "A" and not "The."

V. THE 35 U.S.C. 112, FIRST PARAGRAPH, REJECTION

Claims 37-98, 100-120, 122-135, 137-145, 148-154, 156-158, and 160-186 stand rejected under 35 U.S.C. 112, first paragraph, on the ground that the specification is allegedly not enabling for all types of "substrates." This point was discussed in detail during the interview. Without conceding to the merit of this rejection, and in order to expedite prosecution, the claims have been amended

so as to more specifically define the substrate. In the method claims, the substrate is defined as a belt, sheet, film, foil or tape. In the product claims, the substrate is defined as a sheet, film, foil or tape. New Claims 195-197 (corresponding to Claims 37, 56 and 171, respectively) are directed to the instance where the substrate is a patch. These amendments are supported by the application as originally filed, for example, the discussion appearing at page 3, lines 35-37, page 16, line 4, page 24, lines 5-6 and page 29, lines 24-35. No new matter is entered. Withdrawal of the outstanding lack of enablement rejection is respectfully requested.

VI. THE 35 U.S.C. 112, SECOND PARAGRAPH, REJECTION

Claims 187-190 stand rejected under 35 U.S.C. 112, second paragraph, for the reasons stated on page 4 of the action. As noted earlier, Claims 187-190 have been canceled without prejudice. The 35 U.S.C. 112, second paragraph, rejection has accordingly been rendered moot, and should be withdrawn. Such action is respectfully requested.

VII. THE PRIOR ART REJECTIONS

Claims 98, 113, 114, 115, 116 and 166 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated, or in the alternative, under rejected under

35 U.S.C. 103(a) as allegedly obvious in view of U.S. Patent No. 4,925,670 to Schmidt. Claims 98, 100, 101, 103-109, 113-116, 154 and 166 stand rejected under rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Schmidt. Claims 37, 38, 50-55, 75, 76, 88-92, 169, 171, 176-177, 179 and 184 stand rejected under rejected under 35 U.S.C. 103(a) as allegedly unpatentable over U.S. Patent No. 5,699,649 to Abrams et al. Finally, Claims 37-145 and 148-186 stand rejected under rejected under 35 U.S.C. 103(a) as allegedly unpatentable over WO 92/14451 in view of U.S. Patent No. 5,029,757 to Mlodozeniec et al. Those rejections are respectfully traversed.

As indicated in the Interview Summary Record, agreement was reached during the interview that the claims as amended in the present response obviate the outstanding prior art rejections over Schmidt and Abrams. Those references neither disclose nor suggest the invention as now claimed in this application. Reconsideration and withdrawal of the outstanding prior art rejections based on those two references are accordingly respectfully requested.

The obviousness rejection based on the combined disclosures of WO' 451 in view of Mlodozeniec et al is respectfully traversed. Mlodozeniec describes unit dose forms comprising a web having deposited thereon one or more medicaments, the web being fabricated into an injestible, pharmaceutically and cosmetically acceptable shape and sealed so as to have no exposed

medicament (column 3 lines 14-22). Thus, Mlodozeniec internalizes a medicament within the web to which it has been applied (see also column 4 lines 62-65). The active material is not removable from the web. Column 6 lines 9-10 refer to the web having an unobjectionable "feel" in the mouth, and lines 58-61 indicate that the web must have acceptable taste. Clearly, it is envisaged that the web is injested and that the active material is not removable as a coherent layer or wafer as specified in the present claims. The fabrication to internalize the medicament is a key step of the disclosed process. It is an essential aspect of the process, and one of ordinary skill would not have been motivated to separate this substrate and the active material. After fabrication, the product is unitized into a plurality of unit dosage forms (see claim 1, Fig 1 and column 26 line 14ff).

Mlodozeniec provides no disclosure or suggestion of the removability of the coating layer, and no suggestion of using part of the coating apparatus as a substrate. Likewise, there is no suggestion of either of these features in WO' 451, which also does not disclose applying an active coating. In the absence of any suggestion of the removability of the coating layer, it is clear that one of ordinary skill would not have been motivated to combine those two references in the context of the presently claimed invention. Moreover, one of ordinary skill would not have been motivated to combine the disclosures of WO' 451 and Mlodozeniec and, even if such a combination was attempted (it is

believed that would not have occurred), there is no suggestion of those claims specifying the surface of the coating apparatus (or specifying the conveyor belt). The combination of Mlodozeniec and WO' 451. WO' 451 is primarily concerned with coating a pharmaceutical tablet, whereas Mlodozeniec is concerned with coating a web, fabricating it to internalize the medicament and then dividing into unit dosage units. WO' 451 already starts with the dosage unit. It is submitted that one of ordinary skill would **not** have combined a disclosure of coating a single dosage form with one preparing a single dosage form by coating and later dividing the product. With regard to the Examiner's statement that WO' 451 discloses applying powder "onto a medical substrate which is on a conveyor belt", the medical substrate (usually a tablet) is the substrate being coated, and there is certainly no disclosure or suggestion that the coating on the substrate should be removable. It would seem highly unlikely that one of ordinary skill would want to coat a tablet and then remove the coating.

In summary, one of person of ordinary skill would not have been motivated to resort to the combined disclosures of WO' 451 and Mlodozeniec. Absent any such motivation, it is clear that a *prima facie* case of obviousness is not generated by those disclosures. Reconsideration and withdrawal of the outstanding obviousness rejection are accordingly respectfully requested.

Allowance of the application is awaited.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

37. (Twice amended). [The] A method of coating a substrate which is a belt, sheet, film, foil or tape, the method comprising the step of applying an active coating material to the substrate to form an active coating layer, the active coating material comprising biologically active material, [wherein the active coating layer is removable from the substrate, and] wherein the active coating material is applied electrostatically as a powder, and, after the active coating material is applied, the active coating material is fused to form an active film layer, and wherein the active coating material is removable from the substrate as a wafer comprising the active film layer.

38. (Twice amended). The method according to claim 37, which further includes the step of removing the active coating layer from the substrate as a wafer comprising the active film layer.

56 (Amended). A method of coating a substrate which is a belt, sheet, film, foil or tape, the method comprising the steps of applying [an] one or more coating layers to the substrate, the layer or the first layer being applied directly to

a surface of the substrate, the layer or at least one of the layers comprising active coating material [to the substrate to form an active coating layer], the active coating material comprising biologically active material, [wherein the active coating layer is removable from the substrate, and] wherein the active coating material is applied electrostatically as a powder and after the active coating [layer] material is applied the active coating material is fused to form an active film [coating on the surface of the substrate] layer, and wherein the layer or layers applied are removable from the substrate as a coherent layer or layers.

57. (Twice amended). The method according to claim 56, which further includes the step of removing the active coating layer from the substrate as a wafer comprising the active film layer.

58. (Twice amended). The method according to claim 56, wherein the substrate is [pre-]coated with one or more coating layers removable from the substrate before application of the active coating layer and the active coating layer is removable therewith.

75 (Amended). A method of coating a substrate which is a belt, sheet, film, foil or tape, the method comprising the steps of applying an active coating material to the substrate to form an active coating layer, the active coating material comprising biologically active material, wherein the active coating layer

is removable from the substrate to form a solid dosage form, and the active coating material is applied electrostatically as a powder, and, after the active coating material is applied, the active coating material is fused to form an active film layer, and wherein the active coating material is removable from the substrate as a wafer comprising the active film layer, to form a solid dosage form.

76. (Twice amended). The method according to claim 75, which further includes the step of removing the active coating layer from the substrate as a wafer comprising the active film layer.

93 (Amended). A method of coating a substrate which is a belt, sheet, film, foil or tape, the method comprising the steps of applying [an] one or more coating layers to the substrate, the layer or the first layer being applied directly to a surface of the substrate, the layer or at least one of the layers comprising active coating material [to the substrate to form an active coating layer], the active coating material comprising biologically active material, wherein [the active coating layer is removable from the substrate to form a solid dosage form, and] the active coating material is applied electrostatically as a powder, [and] wherein after the active coating [layer] material is applied the active coating material is fused to form an active film [coating on the surface of the substrate] layer, and wherein the layer or layers applied are removable from the substrate as a coherent layer or layers to form a solid dosage unit form.

98 (Twice amended). A method of coating a substrate using a coating apparatus having a conveying surface, the method including the steps of applying an active coating material to the substrate to form an active coating layer, said substrate being [a] said conveying surface of the coating apparatus, the active coating material comprising biologically active material, wherein the active coating layer is removable from the substrate as a wafer comprising the active coating layer, and wherein the active coating is removed as a wafer comprising the active coating layer.

120 (Twice amended). A method of coating a substrate using a coating apparatus having a conveying surface, the method comprising the steps of applying an active coating material to the substrate to form an active coating layer, said substrate being [a] the conveying surface of the coating apparatus, the active coating material comprising biologically active material, wherein [the active coating layer is removable from the substrate, and] the active coating material is applied electrostatically as a powder, and, after the active coating material is applied, the active coating material is fused to form an active film layer, and wherein the active coating material is removable from the substrate as a wafer comprising the active film layer, and wherein the active [coating] material is removed as a wafer comprising the active film layer.

135 (Twice amended). A method of coating a substrate using a coating apparatus having a conveying surface, the method comprising the steps of applying [an] one or more coating layers to the substrate, the layer or the first layer being applied directly to a surface of the substrate, the layer or at least one of the layers comprising active coating material [to the substrate to form an active coating layer], said substrate being [a] the conveying surface of the coating apparatus, the active coating material comprising biologically active material, wherein [the active coating layer is removable from the substrate, and] the active coating material is applied electrostatically as a powder, and wherein after the active coating [layer] material is applied the active coating material is fused to form an active film [coating on the surface of the substrate] layer, and wherein the layer or layers applied are removable from the substrate as a coherent layer or layers, and wherein the active coating is removed from the substrate as a [wafer] coherent layer or layers.

148. (Twice amended). A method of coating a plurality of coating regions onto the surface of a substrate which is a belt, sheet, film, foil or tape, the method comprising the steps of:

(a) applying an active coating material to [a surface of] the substrate to form a plurality of active coating regions [on the surface] comprising active coating layers, the active coating material comprising biologically active material

and being applied electrostatically as a powder wherein after the active coating material is applied the active coating material is fused to form regions of active film coating,

(b) applying a cover coating material to a surface of the substrate to form a plurality of cover coating regions, the cover coating regions forming layers of cover coating material, each active coating region being substantially completely covered by a cover coating region, wherein each region of active coating and cover coating is removable from [the surface of] the substrate as a wafer comprising the active film coating and the cover coating.

154. (Twice amended). A method of coating a plurality of coating regions onto the surface of a substrate using a coating apparatus having a conveying surface, the method comprising the steps of:

(a) applying an active coating material to [a surface of] the substrate to form a plurality of active coating regions [on the surface] comprising active coating layers, said substrate being [a] the conveying surface of the coating apparatus, the active coating material comprising biologically active material;

(b) applying a cover coating material to a surface of the substrate to form a plurality of cover coating regions, the cover coating regions forming layers of cover coating material, each active coating region being substantially completely covered by a cover coating region, wherein each region of active coating and

cover coating is removable from [the surface of] the substrate as a wafer comprising the active coating and the cover coating, and wherein the active coating regions are removed as wafers each comprising the active coating and the cover coating.

156. (Twice amended). A method of coating a plurality of coating regions onto the surface of a substrate using a coating apparatus having a conveying surface, the method comprising the steps of:

(a) applying an active coating material to [a surface of] the substrate to form a plurality of active coating regions [on the surface] comprising active coating layers, said substrate being [a] the conveying surface of the coating apparatus, the active coating material comprising biologically active material and being applied electrostatically as a powder wherein after the active coating material is applied the active coating material is fused to form regions of active film coating,

(b) applying a cover coating material to a surface of the substrate to form a plurality of cover coating regions, the cover coating regions forming layers of cover coating material, each active coating region being substantially completely covered by a cover coating region, wherein each region of active coating and cover coating is removable from the surface of the substrate as a wafer

comprising the active film coating and the cover coating, and wherein the active coating regions are removed as wafers each comprising the active film coating the cover coating.

162 (Amended). A method of coating a substrate which is a belt, sheet, film, foil or tape, the method comprising the steps of applying an active coating material to the substrate to form an active coating layer, the active coating material comprising biologically active material, wherein [the active coating layer is removable from the substrate, and] the active coating material is applied electrostatically as a powder, and, after the active coating material is applied, the active coating material is fused to form an active film layer, and wherein the active coating material is removable from the substrate as a wafer comprising the active film layer, and wherein the active coating layer is removed from the substrate as a wafer comprising the active film layer and divided into smaller portions.

166 (Twice amended). A method of coating a substrate using a coating apparatus having a conveying surface, the method including the steps of applying an active coating material to the substrate to form an active coating layer, said substrate being [a] the conveying surface of the coating apparatus, the active coating material comprising biologically active material, wherein the active coating layer is removable from the substrate as a wafer comprising the

active coating layer, and wherein the active coating is removed as a wafer comprising the active coating layer and divided into smaller portions.

167 (Twice amended). A method of coating a substrate using a coating apparatus having a conveying surface, the method comprising the steps of applying an active coating material to the substrate to form an active coating layer, said substrate being [a] the conveying surface of the coating apparatus, the active coating material comprising biologically active material, wherein [the active coating layer is removable from the substrate, and] the active coating material is applied electrostatically as a powder, and, after the active coating material is applied, the active coating material is fused to form an active film layer, and wherein the active coating material is removable from the substrate as a wafer comprising the active film layer, and wherein the active coating is removed as a wafer comprising the active film layer and divided into smaller portions.

169 (Amended). A method of coating a substrate which is a belt, sheet, film, foil or tape, the method comprising the steps of applying an active coating material to the substrate to form an active coating layer, the active coating material comprising biologically active material, wherein the active coating [layer] material is removable from the substrate as a wafer comprising the active coating layer, and the active coating material is applied electrostatically as a powder, and

wherein active coating material is applied to a plurality of individual regions on the [surface of the] substrate, wherein after the active coating layer is applied the active coating material is fused to form an active film coating and wherein the amount of active coating material deposited on a given area of the substrate is controlled such that the product can subsequently be divided into portions with each portion containing a pre-determined amount of active coating material, each pre-determined amount being one dose of the active material.

171 (Amended). A coated substrate which is a sheet, film, foil or tape comprising an active coating layer that has been applied electrostatically as a powder on a surface of the substrate and then fused to form an active film layer, the active coating layer including biologically active material and in which the active coating layer is removable from the [surface of the] coated substrate as a wafer comprising the active film layer.

179 (Amended). An intermediate product for use in producing a plurality of solid dosage forms, the intermediate product comprising a substrate ~~which is a~~ sheet, film, foil or tape and active coating comprising biologically active material that has been applied electrostatically as a powder in a plurality of regions on the substrate and then fused to form an active film coating, each region of active coating being removable from the [surface of the] substrate as a wafer comprising the active film coating.

181 (Twice amended). An intermediate product for use in producing a plurality of solid dosage forms, the intermediate product comprising a substrate which is a sheet, film, foil or tape and active coating comprising biologically active material in a plurality of regions on the substrate, [the active coating regions being removable from the surface of the substrate,] wherein each active coating region includes a cover coating region comprising a layer of cover coating material, each active coating region being substantially completely covered by a cover coating region and wherein each region of active coating and cover coating is removable from the surface of the substrate as a wafer comprising the active coating and a cover coating, wherein the active coating has been applied electrostatically as a powder and then fused to form an active film coating.

183 (Twice amended). An intermediate product for use in producing a plurality of solid dosage forms, the intermediate product comprising a substrate which is a sheet, film, foil or tape and active coating comprising biologically active material in a plurality of regions on the substrate, [the active coating regions being removable from the surface of the substrate,] wherein each active coating region includes a cover coating region comprising a layer of cover coating material, each active coating region being substantially completely covered by a cover coating region and wherein each region of active coating and cover coating is removable from the [surface of the] substrate as a wafer comprising the active

coating and cover coating, wherein the active coating [layer] comprises:

i) a continuous phase component;

ii) the biologically active material;

iii) a charge-modifying component; and

iv) a flow aid.

184 (Amended). An intermediate product for use in producing a plurality of solid dosage forms, the intermediate product comprising a substrate which is a sheet, film, foil or tape and active coating material comprising biologically active material that has been deposited electrostatically as a powder on the substrate and then fused to form an active film layer, the amount of active coating material deposited on a given area of the substrate being such that the product can subsequently be divided into portions with each portion containing a predetermined amount of active coating material, each predetermined amount being one dose of the active material, and the active [coating] film layer being removable from the [surface of the] substrate as a wafer comprising the active film layer.